K090464

PT. MAHAKARYA INTI BUANA

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Date : February 10, 2009

510 (K) SUMMARY

APR 23 2009

1.0 Submitter:

Name	:	PT MAHAKARYA INTI BUANA
Address	:	Jl. Sei Belumai, Desa Dalu 10 A Dusun I No. 18 Tanjung Morawa – 20362 SUMUT – INDONESIA
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FDA Registration No	:	3004049816

2.0 Contact Person:

Name	:	(Mr) Azman Ismail
Phone	:	+62-61-30007150,51
Fax No.	:	+62-61-30007156
E-mail	:	qa@mib-ia.com

3.0 Name of the device:

Trade Name	:	1) Senstouch and 2) Multiple or Customers' Trade Name
Device Name	:	Black Nitrile Examination Gloves, Powder Free, Non Sterile
Common Name	:	Patient Examination Gloves
Classification Name	:	Nitrile Examination Gloves

4.0 Identification of The Legally Marketed Device:

Polymer	:	Nitrile Latex
Device Class	:	Class I
Substantial Equivalent		
Device Description	:	Patient Examination Gloves, 21 CFR 880.6250
Product Code	:	Nitrile - 80LZA
Standard	:	ASTM D 6319-00a (2005)

5.0 Performance Testing Standard:

Water Leak Test	:	G-I, AQL 1.5	
Physical Dimension	:	S-2, AQL 4.0	
Physical Properties	:	S-2, AQL 2.5, Single Sampling	
Residual Powder	:	N = 5	
Moisture Content	:	N = 8	
Visual Inspection	:	Critical Defects	AQL 0.65
		Major Defects	AQL 2.5
		Minor Defects	AQL 4.0

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6.0 Intended Use of The Device

Powder-free Black Nitrile Examination Gloves, Non Sterile is a disposable device intended for medical purposes that is worn on the examiner's to prevent contamination between patient and examiner.

7.0 Summary of The Technological Characteristics of The Device (Performance and Conformance Test Data):

Technological characteristics of Black Nitrile Examination Gloves, Powder Free, Non Sterile are summarized as below:-

REQUIREMENT	REFERENCE STANDARDS	DEVICE PERFORMANCE	STANDARD SPECIFICATION
Physical Dimension	D 6319-00a^{E3}	Length = 240.9 mm Width = 97.7 mm Thickness: - Finger = 0.148 mm - Palm = 0.109 mm - Cuff = 0.092 mm	Length ≥ 230 mm Width = 95 ± 10 Thickness ≥ 0.05
Physical Properties	D 6319-00a^{E3}	Unaged: TS = 18.8 MPa UE = 679.4 % Aged: TS = 21.3 MPa UE = 767.4 %	Unaged: TS = 14 MPa UE = 500 % Aged: TS = 14 MPa UE = 400 %
Freedom from Pinholes	D 6319-00a^{E3} FDA 21 CFR 800.20	0 piece found	Acc / Rej = 3 / 4
Moisture Content	In-house	0.46%	0.8%
Powder Residue	D 6319-00a^{E3} D6124 - 01	0.96 mg/glove	< 2.0 mg/glove
Biocompatibility	Primary Skin Irritation in Rabbits	Pass (Negative)	Pass
	Dermal Sensitization	Pass (Negative)	Pass

Table 7.0 Performance and Conformance Data of Black Nitrile Examination Glove

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8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

Based on the above data and information, the device is substantially equivalent to its predicate device approved for distribution in the United States.
Part 4 of this submission discusses further on substantial equivalent comparison

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not required for gloves for this submission.

10.0 Conclusion

It can be concluded that the Black Nitrile Powder Free Nitrile Black Examination Gloves, Non Sterile perform according to the gloves performance standards referenced in Section (5) and (7) above and hence meet ASTM standards and FDA requirements.

Conclusively, we therefore claim that this device is substantially equivalent to its predicate device approved by FDA and is safe and effective for its intended for purposes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2009

Mr. Azman Ismail
Quality Assurance Manager
PT. MAHAKARYA INTI BUANA
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Desa Dalu 10 A Dusun 1 Number 18
Tanjung Morawa - 20362
SUMUT – INDONESIA

Re: K090464
Trade/Device Name: Black Nitrile Examination Gloves, Powderfree, Non-Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: April 13, 2009
Received: April 15, 2009

Dear Mr. Ismail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 090464

Device Name: Black Nitrile Examination Gloves, Powderfree, Non-Sterile

Indications for use:

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use X

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

GCJ for dem

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090464